

REMARKS

Prior to the present amendment, claims 17-59, 67, 68, 70-73, 76-80 and 82-87 were pending. By this amendemnt, applicants have cancelled claims 17-59, 67, 68, 70-73, 76-80 and 82-86, amended claim 87, and added new claims 88-100. Accordingly, claims 87-100 are currently pending.

Claims 17, 18, 70-73, 76-79 and 85-86 were rejected under 35 U.S.C. 102(b) for allegedly being anticipated by Davies et al. (*Thromb. Haemostas*, Suppl: 2352). Claim 20 was rejected under 35 U.S.C. 103(a) for allgedly being obvious over Davies et al. in view of U.S. Patent No. 4,731,245. Further, claims 17 and 67-68 was rejected under 35 U.S.C. 103(a) for allegedly being obvious over Davies et al. in view of Foug et al. (1986, Chapter 13 in *Methods in Enzymology*, vol. 12, pages 168-174) and U.S. Patent No. 5,916,771.

Merely in order to expediate prosecution, applicants have cancelled claims 17-59, 67, 68, 70-73, 76-80 and 82-86. Accordingly, all the art rejections (e.g., 102(b) and 103(a) rejections) are moot and should be withdrawn.

Claim 87 was rejected under 35 U.S.C. 112, first paragraph, allegely for lack of enablement. The examiner contends that the specificalton is not enabled for an isolated polypeptide having a heavy chain variable region containing SEQ. ID. NOs: 24, 26, 31, 33, 35, 37 or 52 and any light chain variable region of a human antibody.

Applicants respectfully disagree. The presence of a heavy chain variable region of a human antibody with factor VIII specificity in the claimed polypeptide ensures that the claimed polypeptide possesses specific binding to factor VIII. It is not required that the light chain variable region be from the same, or different, factor VIII-specific antibody.

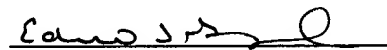
Therefore, the light chain variable region can be any light chain variable region of a human antibody. This is clearly demonstrated in the specification. See for instance, example 2, page 19, line 30 to page 20, line 10. There, it is disclosed the use of the vector pHEN-1-VLrep as a source of light chain variable regions. The vector contains a light chain repertoire derived from two non-immunized donors (i.e., healthy subjects not containing factor VIII-specific antibodies). Single-chain Fv fragments specifically binding to the C2 domain of factor VIII (see examples 2-4), the A3-C1 domain for factor VIII (see example 8), and the A2 domain of factor VIII (see example 9) was obtained using the light chain repertoire.

Thus, the examples disclosed in the specification demonstrate that the light chain variable region can vary without losing factor VIII specificity. Therefore, the claimed polypeptide is clearly enabled.

Accordingly, applicants respectfully request that the rejection of claim 87 under 35 U.S.C. 112, first paragraph be reconsidered and withdrawn.

For the above reasons, allowance of the pending claims is earnestly requested. If the examiner has any questions regarding this amendment, he is invited to contact the undersigned at the telephone number listed below.

Respectfully submitted,



Edna I. Gergel, Ph.D.

Registration No. 50,819

Agent for Applicants

HOFFMANN & BARON, LLP
6900 Jericho Turnpike
Syosset, New York 11791
Tel. 516-822-3550
Fax. 516-822-3582